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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,086	10/30/2003	Ronald H.P. Brus	2578-6158US	9184

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EXAMINER

LUCAS, ZACHARIAH

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 08/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/698,086

Applicant(s)

BRUS ET AL.

Examiner

Zachariah Lucas

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 8,9 and 17-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,7-10 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

1. Claims 1-24 are pending in the application. In the prior action, mailed on February 23, 2005, claims 1-23 were pending, with claims 1-7, 10, and 12-16 under consideration and rejected, and claims 8, 9, 11, 17-23 withdrawn as being drawn to a nonelected inventions. In the Response of June 22, 2005, the Applicant amended claims 1, 2, 7-10, 12, and 17; and added new claim 24. Claim 24 is withdrawn from examination on the same basis as was described with respect to claim 23 in the prior action. I.e., the method is not a method of identifying antiviral agents as in the elected claims, but rather is a method for identifying the effects on a virus by a antiviral compound.

Claims 1-7, 10, and 12-16 are pending and under consideration.

Claim Rejections - 35 USC § 101

2. **(Prior Rejection- Withdrawn)** Claims 1-7, 10, and 12-16 were rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. The claims are rejected because, although the Applicant has provided a utility for the claimed methods to the extent that it reads on the identification of compounds with anti-viral activities, there is no utility provided for compounds with no effect or a positive effect (a pro-viral activity). In view of the amendment of the claims such that they are now drawn to the identification of compounds with anti-viral activity, the rejection is withdrawn.

Claims 1-7, 10, and 12-16 were also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial

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asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. In view of the amendments identified above, this rejection is also withdrawn.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. **(Prior Rejection- Withdrawn)** Claim 7 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite because it was not clear if claim 7 was redundant to claim 1 as amended, or if the claim requires the presence of a nucleic acid encoding an additional adenoviral early protein to the nucleic acid encoding E1 protein required by claim 1. In view of the amendment of the claim, requiring the addition introduction of a nucleic acid encoding the E2 protein, the rejection is withdrawn.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. **(New Rejection- Necessitated by Amendment)** Claims 1-7, 10, and 12-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in

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such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims have been amended to read on methods for the identification of compounds with antiviral activity against any virus "other than an adenovirus." The claims are rejected because the application lacks written descriptive support for the negative limitation excluding adenoviruses from the claimed methods.

Section 2173.05(i) of the MPEP states that "Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement." In the present case, although the application discloses the use of several different types of viruses (see e.g., page 7, paragraph [0028]) and would therefore support claims directed to any one or any combination of these virus types, the application nowhere provides support for the genus of any virus other than adenoviruses. I.e., there is no basis in the application for the exclusion of adenoviruses.

It is suggested that the Applicant amend the claims to read on methods of identifying antiviral agents against those viruses specifically identified on page 7 of the application other than adenoviruses. This is because, while the Applicant may affirmatively limit the claims to the positively identified genera identified in the application, the genera including any virus except adenoviruses lacks support.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. **(Prior Rejection- Maintained)** Claims 1-7, 10, 12, 13, and 16 were rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of Burk et al. (WO 91/15573- of record in the October 2003 IDS) in view of Hateboer et al. (WO 00/63403- of record in the October 2003 IDS). The Applicant traverses the rejection on the basis that Hateboer does not show the use of E1 immortalized cells can be used to propagate viruses other than adenoviruses, and “AT the time of filing, only adenoviruses were thought to be able to infect and propagate in the E1-immortalized cells.” The Applicant concludes from these assertions that because neither the Hateboer or Burk references teach that E1-immortalized cells could sustain viral infections of non-adenoviral viruses, there would have been no motivation in the art to use such cells for the purpose of studying the life-cycles of such viruses. These arguments are not found persuasive.

The Applicant’s assertion that there would be no motivation for those in the art to use the E1 transformed cells of Hateboer in the methods of using immortalized cells described in Burk relies on the Applicant’s assertion that “only adenoviruses were thought to be able to infect and propagate in the E1-immortalized cells” by those of ordinary skill in the art. However, the Applicant made this assertion without any evidential support.

Further, in contrast to this assertion, it is noted that the Burk reference specifically teaches that the cells used in the methods disclosed therein may be transformed using oncogenic viral proteins. Page 9. While the reference teaches the use of viral oncogenes derived from mammalian genes, the teachings of the reference indicate that any oncogene that inhibits the normal cell-replication control mechanisms of the primary cells may be used for cell

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immortalization. Id. The teachings of the art demonstrate knowledge of the oncogenic, and cell-regulation inhibiting, activities of the adenoviral E1 proteins. See e.g., U.S. Patent 5,994,128, column 2. Thus, those in the art would have had a reasonable expectation that the adenoviral E1 proteins would be equally useful in the methods of Burk as the other identified viral oncogenes.

It is noted that, as asserted by the Applicant, the Hateboer reference does not teach the use of cells transformed with the adenoviral oncogene for the replication of other viruses. However, the reference is completely silent as to this utility of the immortalized cells, and provides no teachings to indicate that the cells would not be useful in such methods.

In view of the suggestion in Burk, that cells immortalized with viral oncogenes may be used for the replication and study of viruses in general, and in view of the lack of evidence provided in support of Applicant's assertion regarding what would have been expected by those in the art, the rejection is maintained.

9. **(Prior Rejection- Maintained)** Claims 1-7, 10, 12-14, and 16 were rejected under 35 U.S.C. 103(a) as being unpatentable over Burk and Hateboer as applied to claims 1-3, 5-7, 12, 13, and 16 above, and further in view of Lin et al. (J Virol Methods 88: 219-25). Claim 14, which was not rejected over Burk and Hateboer above, further requires that the compound to be tested is compound from a library. The Applicant traverses this rejection on the same basis as was indicated with respect to the rejection over Burk and Hateboer above. For the reasons indicated above, this traversal is not found persuasive. The rejection is therefore maintained.

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10. **(Prior Rejection- Maintained)** Claims 1-7, and 12-16 are rejected under 35

U.S.C. 103(a) as being unpatentable over Burk and Hateboer as applied to claims 1-3, 5-7, 12, 13, and 16 above, and further in view of Halliday et al. (WO 99/51776- of record in the October 2003 IDS). The Applicant traverses this rejection on the same basis as was indicated with respect to the rejection over Burk and Hateboer above. For the reasons indicated above, this traversal is not found persuasive. The rejection is therefore maintained.

Conclusion

11. No claims are allowed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

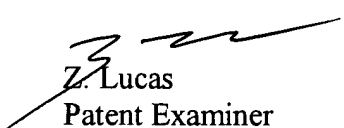
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Z. Lucas
Patent Examiner


JAMES HOUSEL 8/19/05
SUPERVISORY PATENT EXAMINER
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